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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

CORCEPT THERAPEUTICS, INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

**Civil Action No. 18-3632 (SDW)(CLW)
(consolidated)**

REDACTED VERSION

Filed Electronically

**DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S BRIEF IN
OPPOSITION TO CORCEPT'S MOTION FOR SUMMARY JUDGMENT OF
INFRINGEMENT OF U.S. PATENT NO. 10,195,214
AND IN SUPPORT OF CROSS-MOTION FOR SUMMARY JUDGMENT OF
NON-INFRINGEMENT OF U.S. PATENT NO. 10,195,214**

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INTRODUCTION

In asking for summary judgment of infringement, Corcept boldly but incorrectly claims that the FDA-approved label for Teva’s proposed mifepristone product instructs and encourages medical professionals to carry out every step of the asserted claims of the ’214 patent. But Teva’s proposed label neither instructs nor encourages medical professionals to perform perhaps the most important step in the claims—namely, administering a strong CYP3A inhibitor to a Cushing’s syndrome patient who is already taking mifepristone. On the contrary, Teva’s proposed label warns against the practice because it can result in increased blood plasma levels of mifepristone.

To be sure, Teva’s label tells medical professionals that, *if they decide* to administer a strong CYP3A inhibitor to a Cushing’s patient who is already taking mifepristone, then they should reduce the dose of mifepristone. Controlling Federal Circuit precedent makes it clear, however, that an instruction in the form “if you do X, then do Y” is *not* an instruction to do X.

See HZNP Medicines LLC v. Actavis Labs. UT, Inc., 940 F.3d 680, 702 (Fed. Cir. 2019).

This black-letter law rests on sound common sense. If I tell my teenage son who is about to go out to a party, “If you get drunk tonight, then take a cab or Uber home,” I am not instructing or encouraging my son to get drunk. In fact, that advice is entirely consistent with me desiring that my son should not get drunk and should not need to take a cab or Uber home. But—in case my son does not respect my wishes—I issue the advice.

So, too, here: encouraging physicians to reduce the dose of mifepristone if they deem it appropriate to administer a strong CYP3A inhibitor is *not the same thing* as encouraging them to administer a strong CYP3A inhibitor in the first place. Physicians could comply fully with the instruction on Teva’s label without ever administering a strong CYP3A inhibitor together with mifepristone in a Cushing’s patient. Corcept’s own clinical expert, for example, is a physician

who has treated many Cushing’s patients with mifepristone in accordance with the Korlym label (which is substantively identical to Teva’s proposed label) but yet has never co-administered a strong CYP3A inhibitor with mifepristone. That the label anticipates the possibility that some physicians might decide to administer a strong CYP3A inhibitor with mifepristone does not reflect the requisite specific intent or the requisite encouraging action to actively induce infringement. “Merely describing the infringing use, or knowing of the possibility of infringement, will not suffice; specific intent and action to induce infringement must be shown.” *Id.* Because Teva’s proposed label does not encourage or instruct anyone to administer a strong CYP3A inhibitor, the label does not actively induce infringement of the patent as a matter of law.

Teva respectfully requests that the Court deny Corcept’s motion and grant Teva’s cross-motion for summary judgment that Teva does not infringe the ’214 patent.

BACKGROUND

A. Procedural history

This lawsuit arises from Teva’s application for FDA approval to market a generic version of Corcept’s product Korlym (mifepristone). Mifepristone is an old drug. It was developed in 1980 under the name RU-486 as an abortion pill. By the mid-1980s, researchers discovered that the drug could also be useful in the treatment of Cushing’s syndrome. In 2012, the FDA approved Korlym to treat certain patients with Cushing’s syndrome, a disease characterized by high cortisol levels. Corcept SUMF ¶ 3.

The approved indication for Korlym is very specific: Korlym is “indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing’s syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.” Teva SUMF ¶ 15. Because the only approved indication for Korlym is so narrow and specific, Corcept applied for and received orphan-drug exclusivity for

Korlym, meaning that the FDA would not grant final approval to any generic competitor for an additional seven years (which, in Korlym's case, meant February 2019). Corcept SUMF ¶ 3.

Corcept sued Teva in 2018, asserting the only two patents that were then listed in the Orange Book for Korlym: U.S. Patent No. 8,921,348 and U.S. Patent No. 9,829,495. Dkt. 1. Both patents claim methods of using mifepristone (albeit not any methods of using mifepristone recited in the Korlym label). *See id.* Corcept later added other patents to the suit, including the '214 patent at issue in this motion. *See Corcept Therapeutics v. Teva Pharm. USA, Inc.*, No. 19-cv-5066 (D.N.J. filed Feb. 8, 2019); *see also* Dkt. 59.

In early 2021, Corcept dropped the originally asserted '348 and '495 patents from the case. Ex. 6.¹ This move did not come as a surprise; Corcept's own CFO candidly admitted on a public earnings call that those two patents do not read on the Korlym label (meaning Corcept should never have listed them in the Orange Book—or sued on them—in the first place, and thus should never have enjoyed the benefit of a 30-month stay). *See* Ex. 5 at CORMIFE-T-00039518.

B. Corcept's asserted '214 patent

The '214 patent relates to methods of co-administering mifepristone and strong CYP3A inhibitors. The specification describes methods of treating Cushing's syndrome and associated conditions by concomitantly administering glucocorticoid receptor modulators (such as mifepristone) and CYP3A inhibitors (such as ketoconazole). '214 patent (Ex. A) Abstract.²

At the time of the purported invention, skilled artisans knew that both ketoconazole and mifepristone could be used to treat Cushing's syndrome. *Id.* 1:43–49, 2:26–27. Ketoconazole,

¹ Unless otherwise indicated, numbered exhibits refer to the exhibits attached to the accompanying Declaration of Liza M. Walsh.

² Unless otherwise indicated, lettered exhibits refer to the Declaration of Nicolas A. LoCastro submitted in support of Corcept's Motion for Summary Judgment of Infringement of U.S. Patent No. 10,195,214 (Dkt. 198-01).

however, is a strong inhibitor of CYP3A gene products, *id.* 12:14–20, and mifepristone is a CYP3A substrate (i.e., it is metabolized by CYP3A enzymes), Corcept SUMF ¶¶ 4–5. Co-administration of a CYP3A inhibitor and a CYP3A substrate (such as mifepristone) to a patient can decrease the metabolism and thus increase the blood plasma concentration of the CYP3A substrate in the patient. '214 patent, 3:16–32, 12:14–16, 13:53–63, 34:8–23. Accordingly, co-administration can present a risk of toxic effects. *Id.* 3:16–32.

The '214 patent discloses Corcept's allegedly "surprising[]" discovery "that concomitant administration of mifepristone and ketoconazole causes only a small increase" in mifepristone plasma concentrations. *Id.* 12:26–38. Based on this purportedly surprising discovery, the specification concludes that mifepristone and "other glucocorticoid receptor antagonists[] may be safely administered concomitantly with CYP3A enzyme inhibitors" to treat Cushing's syndrome. *Id.* 12:63–66, 13:53–63, 14:4–10.

Each asserted claim of the '214 patent requires administering mifepristone to a patient, reducing the mifepristone dose, and then administering a strong CYP3A inhibitor to the patient. For example, independent claim 1 claims the following method:

A method of treating Cushing's syndrome in a patient who is taking an original once-daily dose of 1200 mg or 900 mg per day of mifepristone, comprising the steps of:

reducing the original once-daily dose to an adjusted once-daily dose of 600 mg mifepristone,

administering the adjusted once-daily dose of 600 mg mifepristone and a strong CYP3A inhibitor to the patient,

wherein said strong CYP3A inhibitor is selected from the group consisting of ketoconazole, itraconazole, nefazodone, ritonavir, nelfmavir, indinavir, boceprevir, clarithromycin, conivaptan, lopinavir, posaconazole, saquinavir, telaprevir, cobicistat, troleandomycin, tipranavir, paritaprevir and voriconazole.

Id. at 68:2–16; *see also* Corcept SUMF ¶¶ 10–11. Independent claims 5 and 10 are essentially

identical to claim 1, except that the preamble of claim 5 recites “[a] method of treating symptoms associated with elevated cortisol levels in a patient,” and the preamble of claim 10 recites “[a] method of controlling hyperglycemia secondary to hypercortisolism in a patient with endogenous Cushing’s syndrome.” ’214 patent, 68:23–38, 68:47–63; *see also* Corcept SUMF ¶ 10.

Each asserted claim of the patent thus requires three steps: (i) administering mifepristone; (ii) reducing the mifepristone dose; and (iii) administering a strong CYP3A inhibitor. *See* Teva SUMF ¶¶ 7–10; Ex. 3 (Carroll) 159:4–160:3.

C. Teva’s proposed ANDA product

The label for Teva’s proposed ANDA product is identical to the Korlym label in all material respects. Corcept SUMF ¶ 20. Both labels provide instructions for the administration of mifepristone according to its FDA-approved indication: to “control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing’s syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.” Ex. U § 1; Corcept SUMF ¶ 21.

Section 2 of Teva’s label, titled “Dosage and Administration,” provides that “[t]he recommended starting dose is 300 mg orally once daily.” Ex. U § 2.2; Corcept SUMF ¶ 22; Teva SUMF ¶ 31. “The daily dose of mifepristone tablets may be increased in 300 mg increments. The dose of mifepristone tablets may be increased to a maximum of 1,200 mg once daily but should not exceed 20 mg/kg per day.” Ex. U § 2.2; Corcept SUMF ¶ 22; Teva SUMF ¶ 32.

Teva’s proposed label does not encourage co-administration of mifepristone with strong CYP3A inhibitors. If anything, it warns about potential hazards of co-administration and cautions against it unless doing so is medically necessary. Teva SUMF ¶¶ 21–29. The Dosage and Administration section of the label—cross-referencing the “Warnings and Precautions” section—cautions that “[k]etoconazole and other strong inhibitors of CYP3A . . . may increase

exposure to mifepristone. Mifepristone tablets should be used in combination with strong CYP3A inhibitors only when necessary [*see Warnings and Precautions (5.6), Drug Interactions (7.2)*.]” Ex. U § 2.5; Teva SUMF ¶ 23–24. The label provides the following table specifying the “[a]djustment to dose of mifepristone tablets if adding a strong CYP3A inhibitor”:

A large black rectangular redaction box covers a table from the Teva SUMF label. The table was intended to show the adjustment of mifepristone dose when adding a strong CYP3A inhibitor.

Ex. U Table 1; Teva SUMF ¶ 30.

Section 5, titled “Warnings and Precautions,” provides an additional warning. In a subsection entitled “Use of Strong CYP3A Inhibitors,” the label warns that “[m]ifepristone should be used with caution in patients taking ketoconazole and other strong inhibitors of CYP3A . . . as these could increase the concentration of mifepristone in the blood. The benefit of concomitant use of these agents should be carefully weighed against the potential risks. Mifepristone should be used in combination with strong CYP3A inhibitors only when necessary, and in such cases the dose should be limited to 900 mg per day.” Ex. U § 5.6; Teva SUMF ¶ 26.

Section 7 of the label, titled “Drug Interactions,” similarly provides that “[m]edications that inhibit CYP3A could increase plasma mifepristone concentrations and dose reduction of mifepristone may be required. Ketoconazole and other strong inhibitors of CYP3A . . . may increase exposure to mifepristone. . . . The benefit of concomitant use of these agents should be carefully weighed against the potential risks. The dose of mifepristone should be limited to 900 mg, and strong inhibitors of CYP3A should be used only when necessary.” Ex. U § 7.2; Teva SUMF ¶ 28.

LEGAL STANDARDS

A. Summary judgment

Summary judgment is appropriate if the moving party “shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant; it is material if, under the substantive law, it would affect the outcome of the suit. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

“Since the ultimate burden of proving infringement rests with the patentee, an accused infringer seeking summary judgment of noninfringement may meet its initial responsibility either by providing evidence that would preclude a finding of infringement, or by showing that the evidence on file fails to establish a material issue of fact essential to the patentee’s case.”

Novartis Corp. v. Ben Venue Labs., Inc., 271 F.3d 1043, 1046 (Fed. Cir. 2001); *see also In re Bressman*, 327 F.3d 229, 238 (3d Cir. 2003). The patent owner must then point to “specific facts showing that there is a genuine issue for trial.” *Novartis*, 271 F.3d at 1046; *see also Jersey Cent. Power & Light Co. v. Lacey Township*, 772 F.2d 1103, 1109 (3d Cir. 1985).

B. Induced infringement under the Hatch-Waxman Act

Under 35 U.S.C. § 271(b), a defendant is liable for patent infringement only if it “actively induces infringement of a patent.” “To prove inducement, a plaintiff must present evidence of active steps taken to encourage direct infringement; mere knowledge about a product’s characteristics or that it may be put to infringing uses is not enough.” *HZNP*, 940 F.3d at 701 (citing *Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 630–31 (Fed. Cir. 2015)); *see also DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc) (“[I]nducement requires evidence of culpable conduct, directed to encouraging another’s

infringement, not merely that the inducer had knowledge of the direct infringer’s activities.”).

In the Hatch-Waxman context, the inducement inquiry focuses on the language of the proposed generic drug label. *See Takeda*, 785 F.3d at 631. The question is “whether the proposed label ‘encourages, recommends, or promotes infringement.’” *HZNP*, 940 F.3d at 701–02 (quoting *Takeda*, 785 F.3d at 631). “Merely describing the infringing use, or knowing of the possibility of infringement, will not suffice; specific intent and action to induce infringement must be shown.” *Id.* at 702.

ARGUMENT

I. Teva will not induce infringement as a matter of law.

A. Teva’s proposed label does not recommend, encourage, or promote co-administration of a strong CYP3A inhibitor with mifepristone.

Teva can be held liable for inducement only if its label recommends, encourages, or promotes the patented method. Here, the patented method requires a prescriber to administer a strong CYP3A inhibitor to a patient who is also taking mifepristone. *See Ex. A.* But Teva’s label nowhere recommends administration of a strong CYP3A inhibitor along with mifepristone. At most, the label describes what a physician should do *if* he or she decides on that course of action. Table 1 of Teva’s label—on which Corcept relies for its infringement argument—is explicit on this point: “Adjustment to dose of mifepristone tablets *if adding a strong CYP3A inhibitor.*” *Ex. U* § 2.5 (emphasis added); Teva SUMF ¶ 30. Under black-letter law, that is insufficient to show inducement: “Merely describing the infringing use” is not enough. *HZNP*, 940 F.3d at 702.

If anything, Teva’s label cautions *against* co-administering strong CYP3A inhibitors with mifepristone. The label notes that “strong inhibitors of CYP3A . . . may increase exposure to mifepristone” and instructs that “[m]ifepristone tablets should be used in combination with strong CYP3A inhibitors only when necessary.” *Ex. U* § 2.5; *see also id.* §§ 5, 7; Teva SUMF

¶¶ 21–29. During prosecution of the '214 patent, Corcept characterized nearly identical language in an earlier version of the Korlym label as teaching skilled artisans “to avoid use of mifepristone with CYP3A inhibitors,” Ex. 4 at CORMIFE-T-00002182; Teva SUMF ¶¶ 12–13, and as “contraindicat[ing]” “[c]ombining CYP3A inhibitors and mifepristone,” Ex. 4 at CORMIFE-T-00002489; Teva SUMF ¶ 14; *cf.* Mot. 6 (quoting the 2012 Korlym Label’s statement that “Korlym should be used with extreme caution in patients taking ketoconazole and other strong inhibitors of CYP3A . . . and in such cases the dose should be limited to 300 mg per day”).

In view of these cautionary statements, it is perhaps unsurprising that Dr. Carroll—Corcept’s expert on infringement of the '214 patent, who has been a practicing endocrinologist for more than 11 years and has treated 50–75 patients with Cushing’s syndrome, including at least 15 with mifepristone—has *never* co-administered mifepristone and a strong CYP3A inhibitor. Ex. 3 (Carroll) 47:9–48:11, 49:1–6, 84:10–21; Teva SUMF ¶¶ 16–19.

Q. In fact, you’ve never co-administered mifepristone with a strong CYP3A inhibitor; right?

A. Yeah, that’s correct. I haven’t experienced every clinical scenario that’s possible or that’s even likely.

Q. And you’ve been practicing for 11 years; right?

A. Over 11 years.

Q. And you’ve treated I think you estimated 50 to 75 patients with Cushing’s syndrome?

A. Exactly.

Q. And yet you’ve never found it medically necessary to co-administer mifepristone with a strong CYP3A inhibitor; right?

THE WITNESS: Yeah, that’s correct.

Ex. 3 (Carroll) 84:5–21 (objections omitted). This bears repeating: Corcept’s *own expert*, an experienced endocrinologist who has prescribed Korlym according to the Korlym label multiple

times, has *never once* practiced the patented method. Indeed, the record contains no evidence of *any* physician ever practicing it.

Dr. Carroll's experience is consistent with the statements of the '214 patent inventor, Dr. Belanoff. Dr. Belanoff stated on a 2016 earnings call that "there really is no reason to combine" mifepristone and ketoconazole because "there really is no additive value" in doing so, and that he was "not seeing people use [Korlym and ketoconazole] together." " Ex. 2 at CORMIFE-T-00039366-67; Teva SUMF ¶ 3-5.

In short, Corcept's contention (at 9, 11) that "the language and data in the Dosage and Administration and Clinical Pharmacology sections of Teva's package insert plainly instruct a physician to perform each and every step of the methods claimed in the '214 patent" is demonstrably false. Teva's label does *not* instruct physicians to administer a strong CYP3A inhibitor along with mifepristone. That is probably why Corcept's own expert, despite having followed the materially identical Korlym label many times, has never done it. In other words, Corcept is attempting to preserve its mifepristone monopoly by arguing that Teva will actively induce physicians to do something that treating physicians virtually *never do*.

At most, Teva's label *permits* co-administration of strong CYP3A inhibitors with mifepristone. But the choice of whether to administer the strong CYP3A inhibitor is entirely up to the physician, based on his or her independent medical judgment. Dr. Carroll expressly admitted as much. *See* Ex. 3 (Carroll) 52:11-14 ("I think that the decision about whether to prescribe in this case mifepristone and a strong CYP3A inhibitor is made by the prescriber."); Teva SUMF ¶ 20.

In other words, prescribers can comply fully with Teva's proposed label regardless of whether any prescriber ever chooses to co-administer mifepristone and CYP3A inhibitors. If a

prescriber, exercising her own judgment, decides to do so, it will not be because of anything Teva's label says. Indeed, as noted above, Teva's label cautions that such co-administration should be avoided to the extent possible. *See Ex. U* § 2.2 ("only when necessary"). There can be no inducement under these circumstances. *See United Therapeutics Corp. v. Sandoz, Inc.*, 2014 WL 4259153, at *21 (D.N.J. Aug. 29, 2014) (finding no inducement where any direct infringement by physicians would be based on the physicians' own medical judgment, not based on instructions from the accused label). To the extent the label suggests anything regarding the desirability of the combination of the two drugs, it warns *against* such co-administration—as Corcept's teaching-away arguments during prosecution implicitly recognized. *See* Teva SUMF ¶¶ 11–14, 21–29.

Corcept repeatedly states that Teva's label provides instructions regarding *how* to reduce the mifepristone dose *if* the physician adds a strong CYP3A inhibitor to the patient's treatment regimen. *See, e.g.*, Mot. 8, 12–14, 16, 24. But that is beside the point. Corcept must show that the label instructs the physician to administer a strong CYP3A inhibitor in the first instance. Corcept does not and cannot make that showing.

B. Binding precedent compels a finding of no inducement.

Federal Circuit law is clear that where—as here—a defendant's drug label merely *permits* an infringing use, but does not recommend, encourage, or promote it, the defendant cannot be held liable for induced infringement. Specifically, an instruction in the form "if you do X, then do Y" is *not* an instruction to do X. These precedents compel a finding in Teva's favor here.

The Federal Circuit's decision in *HZNP* is directly on point, and it is fatal to Corcept's infringement case. There, the defendant Actavis's product label instructed to apply diclofenac sodium to the knee of a patient suffering from osteoarthritis pain. 940 F.3d at 699. The label further instructed to "[w]ait until area is completely dry before covering with clothing or

applying sunscreen, insect repellant, cosmetics, topical medications, or other substances.” *Id.* at 700. Horizon’s asserted patents claimed a method of (i) applying diclofenac sodium to the knee, (ii) waiting for the treated area to dry, and (iii) subsequently applying sunscreen or insect repellant to the treated area. *Id.* at 700–02.

The district court granted summary judgment of no induced infringement, and the Federal Circuit affirmed. The Court explained that

[t]he patented method here requires three distinct steps. The user must: (1) apply the inventive formulation, (2) wait for the area to dry, and (3) apply sunscreen, insect repellant, or a second topical medication. The instructions in Actavis’s label, however, only require the first step of this method, nothing else. . . . The warning, then, operates in an “if/then” manner: *if* the user wants to cover the treated area with clothing or apply another substance over it, *then* the patient should wait until the area is dry. This does not encourage infringement, particularly where the label does not require subsequent application of sunscreen, insect repellant, or a second medication.

Id. at 702 (citations omitted).

The same logic applies here. The ’214 patent claims also require three distinct steps:

(i) administering 900 or 1200 mg mifepristone; (ii) reducing the dose to 600 mg; and (iii) administering a strong CYP3A inhibitor. *See* SUMF ¶¶ 7–10; Ex. 3 (Carroll) 159:4–160:3.

Teva’s proposed label recommends only “the first step of this method, nothing else.” *HZNP*, 940 F.3d at 702; *see* Ex. U §§ 2, 5, 7; Teva SUMF ¶¶ 21–33. The warnings on the label concerning CYP3A inhibitors are just that—warnings—and they operate “in an ‘if/then’ manner: if the user wants to [take a strong CYP3A inhibitor], then the patient should [reduce the mifepristone dose].” *Id.* Dr. Carroll himself said as much:

Q. . . .[F]irst, the clinician makes the determination is it medically necessary to treat this patient with a strong CYP3A inhibitor in addition to mifepristone; is that right?

A. So in a patient that is on mifepristone for their Cushing’s syndrome, *when it’s medically necessary to use a strong CYP3A inhibitor, then that medication can be*

used. Again, if there's no indication to use a strong CYP3A inhibitor, then a strong CYP3A inhibitor is not administered.

Ex. 3 (Carroll) 132:20–133:10 (emphases added); *see also id.* at 118:6–10 (“[I]f mifepristone is administered with a strong CYP3A inhibitor, *then* the instructions on dose adjustment are likely to cause or will cause the prescribing individual to infringe upon that -- the claims in the patent.”) (emphases added).

Accordingly, Teva’s label “does not encourage infringement, particularly where the label does not require subsequent [administration of a strong CYP3A inhibitor].” *HZNP*, 940 F.3d at 702; *see Ex. 3 (Carroll) 167:15–19* (“Well, the label does not require any medication to be used concomitantly; but when it is used concomitantly, there’s instructions on how to adjust the dose and encourages the dosing as laid out in Table 1.”); *id.* at 168:4–5 (admitting that Teva’s label “does not require any drug to be used with mifepristone”). At best, Corcept has “establishe[d] that some users might infringe.” *HZNP*, 940 F.3d at 702.³ But Corcept has not established—and cannot establish—that “the proposed label instructs users to perform the patented method.” *Id.* (quoting *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010)).

Tellingly, Corcept relegates *HZNP*—by far the most factually on-point Federal Circuit precedent—to the back of its brief. And Corcept’s strained attempts to distinguish *HZNP* are meritless.

First, Corcept argues (at 19–20) that the *HZNP* court did not mean what it said when it stated (three separate times) that the proposed generic label would not induce infringement because it did not “require subsequent application of other products.” 940 F.3d at 702. Corcept complains (at 19–20) that the law cannot “demand a showing that the proposed generic label

³ Corcept arguably has not even made that showing, given that neither its own expert nor any other expert in this case has testified to practicing the patented method.

requires that the healthcare provider administer any particular drug in accordance with a patented method” because “no package insert ever *requires* a healthcare provider to administer any given drug.”

That is a non sequitur. It is surely true that drug labels do not *require* physicians to do anything—the physician can always choose not to follow the label. (On this logic, Teva’s proposed label does not “require” administration of mifepristone. *See* Ex. 3 (Carroll) 33:13–20. But the question for inducement purposes is whether the label—*assuming the physician chooses to follow it*—requires each step of the patented method. *See HZNP*, 940 F.3d at 702 (label did not induce application of a second substance because it merely “operate[d] in an ‘if/then’ manner: *if* the user wants to cover the treated area with clothing or apply another substance over it, *then* the patient should wait until the area is dry”).

Here, the answer to that question is indisputably no: a physician who follows Teva’s proposed label may choose *never* to administer a strong CYP3A inhibitor along with mifepristone. Indeed, avoiding co-administration is what the label recommends: the “Warnings and Precautions” section states that “[t]he benefit of concomitant use of these agents should be carefully weighed against the potential risks” and that “[m]ifepristone should be used in combination with strong CYP3A inhibitors only when necessary.” Ex. U § 5; SUMF ¶ 26. And, again, Corcept’s own expert, who has been prescribing mifepristone to patients according to the approved drug label for a decade, has never practiced the patented method.

Corcept’s reliance (at 20–21) on *Forest Laboratories Holdings Ltd. v. Mylan Inc.*, 206 F. Supp. 3d 957 (D. Del. 2016), in support of its attempt to distinguish *HZNP* fails as well. In *Forest*, the patent claimed a particular titration schedule of milnacipran. *Id.* at 976. The label for the defendants’ milnacipran product set forth a single titration schedule, which mapped directly

onto the asserted claim. *Id.* at 977. The court found this sufficient to show inducement. And it rejected the defendants' argument that they could avoid liability simply because the label stated that the drug "may" be titrated according to the patented method. *Id.* at 977–78. Thus, in *Forest*, a physician following the label would necessarily practice the patented titration schedule; the label set forth no other method of titration. Here, in contrast, physicians following the label will inevitably administer mifepristone—but they will *not* inevitably administer strong CYP3A inhibitors along with it.

Second, Corcept asserts (at 21) that Teva is liable for inducement because (i) co-administration of mifepristone and strong CYP3A inhibitors will sometimes be "necessary" and (ii) Teva's label "instructs *one and only one* course of action when adding a strong CYP3A inhibitor to the treatment regimen of a patient already receiving a 900 mg mifepristone dose." But *HZNP* considered and rejected precisely this argument. In that case, Horizon argued that "application of sunscreen" was sometimes "medically necessary" and that, "when such need arises, Actavis's instruction will lead to an infringing use." 940 F.3d at 701. The Federal Circuit soundly rejected this logic. Horizon conceded "that not all patients who follow the instructions in Actavis's label will engage in an infringing use by applying sunscreen, insect repellent, or a second medication." *Id.* at 702. Accordingly, all Horizon had established was "the 'mere existence of direct infringement.'" *Id.* (quoting *Takeda*, 785 F.3d at 631). The label "merely provided guidance to patients about what to do *if* the patient desired to have anything come into contact with the knee after application of the medication." *Id.* (emphasis added). This "if/then" language was insufficient: Actavis's label's instruction that "*if* the user wants to cover the treated area with clothing or apply another substance over it, *then* the patient should wait until the area is dry" did "not encourage infringement." *Id.* at 702.

This Court should reject Corcept’s argument for the same reasons. Not all physicians who follow the Teva label will administer a strong CYP3A inhibitor to a patient taking mifepristone; on the contrary, the evidence suggests that actual infringement will be rare or nonexistent. Teva’s label simply provides guidance to physicians about what to do *if* they decide, in the exercise of their own medical judgment, to co-administer the two drugs. That is insufficient to establish inducement here, just as the similar instructions in Actavis’s label was insufficient to establish inducement in *HZNP*.

Third, Corcept contends (at 22–23) that *HZNP* is “distinguishable on its facts” because “unlike *HZNP*, the dose titration instructions in Teva’s package insert . . . provide specific prescribing information directed to healthcare providers, not a generalized warning to patients.” This “distinction” makes no sense. The label in *HZNP* instructed that, *if* the patient applied a second substance after the diclofenac, *then* the patient needed to wait for the treated area to dry first (which would have infringed). The label here instructs that, *if* the physician administers a strong CYP3A inhibitor to a patient taking mifepristone, *then* the physician needs to reduce the mifepristone dose (which would infringe). This sort of “if/then” instruction was not enough for inducement in *HZNP*, and it is not enough for inducement here.

Corcept appears to be suggesting that the *HZNP* instructions were directed primarily to patients (because the patient would be applying the second medication), whereas the instructions here are directed primarily to physicians (because the physician would be choosing to administer a strong CYP3A inhibitor). But the audience of a particular statement on the label is irrelevant. The relevant question is whether the statement—to whomever it is directed—encourages infringement. *HZNP* plainly shows Teva’s label here does not.

Grunenthal GmbH v. Alkem Laboratories Ltd., 919 F.3d 1333 (Fed. Cir. 2019), likewise

demonstrates that summary judgment of non-infringement is appropriate here. In that case, the patented method involved using tapentadol to treat polyneuropathic pain. *Id.* at 1336. The generic drug labels stated that the accused tapentadol products were indicated for “pain severe enough to require daily, around-the-clock, long-term opioid treatment.” *Id.* at 1339. It was undisputed that this “severe chronic pain” indication encompassed *both* polyneuropathic pain and other types of pain (mononeuropathic and nociceptive pain). *Id.* Based on those facts, the Federal Circuit held that “the proposed ANDA labels d[id] not specifically encourage use of tapentadol hydrochloride for treatment of polyneuropathic pain.” *Id.*; *see also id.* at 1340 (“proposed labels . . . do not implicitly or explicitly encourage or instruct users to take action that would inevitably lead to use of tapentadol hydrochloride for treatment of polyneuropathic pain”).

A similar conclusion is appropriate here. Like the proposed labels in *Grunenthal*, Teva’s proposed label here at most permits an infringing use (among other uses), but it does not “specifically encourage” an infringing use, *id.* at 1339. It thus does not induce infringement.

C. District-court cases likewise demonstrate that Teva is not liable for inducement.

District-court cases—including ones from this district—are, unsurprisingly, in accord with the Federal Circuit precedent discussed above. *Shire, LLC v. Amneal Pharmaceuticals, LLC*, 2014 WL 2861430 (D.N.J. June 23, 2014), is particularly instructive. There, the patent claims were directed toward a method of treating ADHD in a subject by administering a given drug product “with intake of food by said subject.” *Id.* at *4. Amneal’s proposed drug label, however, said “that the products may be taken ‘with or without food.’” *Id.* at *5. The court granted summary judgment of no induced infringement because “the statement that the medication may be taken with or without food cannot be reasonably understood to be an instruction to engage in an infringing use.” *Id.* The label, the court explained, was “indifferent to

which option is selected. At most, it may be understood to permit an infringing use, but permission is different from encouragement.” *Id.*

Teva’s non-infringement position here is even stronger than Amneal’s was in *Shire*. Teva’s proposed label is not merely “indifferent” to whether a strong CYP3A inhibitor should be co-administered with mifepristone; instead, the label warns *against* such co-administration unless medically necessary. If the indifference in *Shire* was insufficient for inducement liability, then the language in Teva’s label is certainly insufficient. *See also Novartis Pharm., Corp. v. Wockhardt USA LLC*, 2013 WL 5770539, at *9 (D.N.J. Oct. 23, 2013) (Wigenton, J.) (noting that a defendant’s knowledge of actual infringement “is legally irrelevant” if the defendant’s proposed label does not induce infringement).

The District of Minnesota recently reached the same conclusion on analogous facts, granting summary judgment of non-infringement where the accused product’s instructions “characterized as optional” several “required steps” of the patented method. *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, 2021 WL 1111074, at *6–8 (D. Minn. Mar. 23, 2021). Relying on *HZNP*, the court explained that a patentee cannot show inducement based on product instructions “if those instructions expressly describe as optional the performance of a step that is necessary to infringe the patented method.” *Id.* That principle likewise controls this case.

Otsuka Pharmaceutical Co. v. Torrent Pharmaceuticals Ltd., 99 F. Supp. 3d 461 (D.N.J. 2015), is also on point. There, the claims required administering aripiprazole with citalopram or escitalopram. *Id.* at 483. The “Drug Interactions” section of the defendants’ labels stated that “[n]o dosage adjustment of escitalopram is required when aripiprazole is added to escitalopram.” *Id.* at 487. The court held that this statement was insufficient to show inducement: “a warning is just that—a warning. It is not an instruction to co-administer aripiprazole with any

particular drug, much less escitalopram or citalopram.” *Id.* at 490; *see also id.* at 494 (labels were at most “indifferent” to the prospect of co-administration). “[I]ncidental references to even infringing uses in [the warnings] sections” of a proposed label, the court explained, are “insufficient to constitute instruction or encouragement, as opposed to mere permission” and cannot serve “as a basis for inducement liability.” *Id.* at 490; *see also United Therapeutics*, 2014 WL 4259153, at *18 (“[T]he Court finds that the warnings in Sandoz’s label do not amount to an implicit instruction. . . . [T]here is a rather significant difference between a warning and an instruction. A warning provides information regarding a potential risk. It does not prescribe a course of action. An instruction, on the other hand, is a statement directing one to take some action, such as how to avoid a potential adverse event.”).

Just so here. Teva’s label warns of potential adverse consequences of co-administering mifepristone and strong CYP3A inhibitors and cautions prescribers not to do so unless it is medically necessary. This warning is just that—a warning. It is not a recommendation to perform the patented method.

Even Corcept’s own district-court cases prove Teva’s point: a product instruction that merely describes the infringing method—but does not encourage it—is not sufficient to show inducement. For example, the district court in *BTG International Ltd. v. Amneal Pharmaceuticals LLC*, 352 F. Supp. 3d 352 (D.N.J. 2018) (cited at Mot. 11, 17), explained that courts cannot infer intent from the label’s content where “the infringing use [is] no more than an option.” *Id.* at 398; *see also id.* (citing *Shire* for the proposition that there is no inducement where “[c]onsistent with the label, physicians could, at their option, infringe or not infringe”). The *BTG* court simply found that principle inapplicable on its particular facts because, in that case, “[t]he *only* way to follow the[defendants’] labels” was to engage in the patented use. *Id.*

Similarly, the court in *Amarin Pharma, Inc. v. Hikma Pharmaceuticals USA Inc.*, 449 F. Supp. 3d 967 (D. Nev. 2020) (cited at Mot. 22, 24), observed that “[t]he fact that some physicians will infringe when they read and follow the [accused] labels is necessary, but not sufficient to show inducement based on those labels.” *Id.* at 999. Again, the court found infringement only because the label went *beyond* merely permitting infringement and expressly encouraged it. *See id.* at 1000–05.⁴

D. Corcept’s authorities are inapposite.

At various points in its brief, Corcept attempts to analogize the facts here to cases in which courts have held that an ANDA applicant’s label language induced infringement. The stark differences between those cases and this case illustrate why Teva is *not* liable for inducement.

In *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018) (cited at Mot. 17, 20, 24), the patent claimed a method of treatment of schizophrenia by (i) testing the patient to determine whether she was a CYP2D6 poor metabolizer and (ii) administering a dosage of iloperidone to the patient of 12 mg/day or less for poor metabolizers and 12–24 mg/day for non-poor metabolizers. *Id.* at 1121. The defendant’s proposed drug label instructed physicians to administer “12 to 24 mg/day” iloperidone and further instructed that “the ‘iloperidone dose should be reduced by one-half for poor metabolizers of CYP2D6.’” *Id.* at 1122. The label elsewhere emphasized that poor metabolizers “should have their dose reduced by one-half” and that “[l]aboratory tests are available to identify CYP2D6 PMs [poor metabolizers].” *Id.* at 1131. The Federal Circuit held that “the district court

⁴ The *Amarin* court found the asserted patents invalid, *see Amarin*, 449 F. Supp. 3d at 1014, and the Federal Circuit summarily affirmed. 819 F. App’x 932 (Fed. Cir. 2020). The Federal Circuit thus did not have occasion to address the district court’s infringement analysis.

did not clearly err in finding that [this language] ‘recommends that practitioners perform or have performed a genotyping assay to determine whether patients are CYP2D6 poor metabolizers’” and then administer 12 mg/day or less for poor metabolizers and 12–24 mg/day for non-poor metabolizers. *Id.* at 1131–32.

Thus, in *Vanda*, administering the product according to the approved indication led directly to the infringing method. That is not so here. A prescriber administering mifepristone according to the instructions in Teva’s label may *never* co-administer a strong CYP3A inhibitor. Indeed, that is what the label recommends: physicians should avoid such co-administration if they can possibly do so.

In *AstraZeneca*, 633 F.3d 1042 (cited at Mot. 10), the patent claimed a method of administering a composition via nebulizer once per day. *See id.* at 1046. The label for Apotex’s proposed generic did not “explicit[ly] mention . . . once-daily administration” but did instruct that the patient should begin with two daily doses of 0.25 mg each and then “downward-titrate to the lowest effective dose once asthma stability is achieved.” *Id.* at 1047, 1057. The Federal Circuit held that this language induced infringement because the downward-titration language necessarily instructed users to infringe: “the first step in titrating down from [0.25 twice daily] would have to be 0.25 mg once daily, as there was no way of decreasing the amount of each dose below 0.25 mg.” *Id.* at 1057.

The instructions here, in contrast, do not necessarily result in infringement. *See* Ex. 3 (Carroll) 83:14–22 (“Q. But it won’t always be medically necessary to co-administer a strong CYP3A inhibitor, right? A. Well, of course not. It will never always be mandatory to do that. Most patients that take mifepristone just take mifepristone without a strong CYP3A inhibitor.”). A physician following the instructions could easily choose never to administer a strong CYP3A

inhibitor in conjunction with mifepristone. For proof on that point, one need look no further than Corcept’s own infringement expert, who has prescribed Korlym 15 times—each time “follow[ing] the instructions that are in that label,” *id.* at 48:7–11—but has never attempted the patented method.

In *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357 (Fed. Cir. 2017) (cited at Mot. 18, 20, 24), the patent was directed to methods of treating patients with pemetrexed in combination with folic acid. *See id.* at 1362. The proposed ANDA label contained various instructions for physicians to “[i]nstruct patients to initiate folic acid,” and “[i]nstruct patients on the need for folic acid . . . supplementation,” as well as instructions for patients stating that “you must also take folic acid prior to and during your treatment” and that “[i]t is very important to take folic acid and vitamin B12 during your treatment with pemetrexed to lower your chances of harmful side effects.” *Id.* at 1364. The Court held that the “repeated instructions” to take the drug in combination with folic acid were “unambiguous on their face and encourage or recommend infringement.” *Id.* at 1369.

Teva’s label here, in contrast, contains no instructions to administer a strong CYP3A inhibitor in the first instance—much less the unambiguous, repeated, mandatory instructions in the label in *Lilly*. On the contrary, Teva’s proposed label repeatedly recommends against administering a strong CYP3A inhibitor to a patient taking mifepristone if possible.

In *Braintree Laboratories, Inc. v. Breckenridge Pharmaceutical, Inc.*, 688 F. App’x 905 (Fed. Cir. 2017) (cited at Mot. 17, 20, 24), the patent was directed to a composition for “inducing purgation of the colon of a patient.” *Id.* at 906. The ANDA applicant “concede[d] that its proposed product ‘cleanses the colon of a patient by inducing purgation’ when taken as directed by its label.” *Id.* at 909. The Court found that the proposed label recommended inducing

purgation as claimed by the patent because that was the sole method by which the product cleansed the colon. *Id.* at 909–10.

Teva’s label here, in contrast, does not necessarily result in infringement when the FDA-approved indication is followed. Quite the contrary: a physician can follow the instructions on the label for a decade or more (as Corcept’s expert has) and never perform the patented method.

Finally, *Sanofi v. Watson Laboratories Inc.*, 875 F.3d 636 (Fed. Cir. 2017) (cited at Mot. 11, 17), *Bone Care International, L.L.C. v. Roxane Laboratories, Inc.*, 2012 WL 2126896 (D. Del. June 11, 2012) (cited at Mot. 11), and *Hoffman-La Roche Inc. v. Apotex, Inc.*, 2010 WL 3522786 (D.N.J. Sept. 2, 2010) (cited at Mot. 17, 18), merely stand for the proposition that the existence of substantial non-infringing uses does not preclude a finding of inducement. *See Sanofi*, 875 F.3d at 646; *Bone Care*, 2012 WL 2126896, at *30; *Hoffman-La Roche*, 2010 WL 3522786, at *4. That principle does not help Corcept here. To be sure, mifepristone does have substantial non-infringing uses—in fact, Corcept has presented no evidence of *any* instance of an actual infringing use. But that is not the point. The point is that Teva’s proposed label does not recommend, encourage, or promote co-administration of mifepristone and strong CYP3A inhibitors. That simple, indisputable fact is fatal to Corcept’s infringement case.

E. [REDACTED]

Corcept suggests (at 21) that the Court can somehow infer intent to induce infringement because [REDACTED] [REDACTED] This argument fails at the outset because, as discussed at length above, the dose-titration steps in the proposed label do not in fact induce infringement: they never encourage the administration of a strong CYP3A inhibitor in the first instance.

[REDACTED] fails for an additional reason relating to Corcept’s abuse of

the FDA’s “use code” system. When an NDA holder lists a method-of-use patent in the Orange Book, it must submit a so-called “use code,” which must correspond to—and be no broader than—the use claimed by the patent. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012); Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. 69580, 69598–99 (Oct. 6, 2016). “[T]he FDA does not attempt to verify the accuracy of the use codes that brand manufacturers supply”; it simply publishes them in the Orange Book. *Caraco*, 566 U.S. at 405–06.

If an ANDA applicant is not seeking approval for the use corresponding to a given patent’s use code, it may “carve out” that use from its label and submit a so-called “section viii” statement. *See* 21 U.S.C. § 355(j)(2)(A)(viii). Importantly, the section viii carve-out path is available *only* if the ANDA applicant’s label does not “overlap[] at all with the brand’s use code.” *Caraco*, 566 U.S. at 406. If there is any overlap, the ANDA applicant must file a Paragraph IV certification instead. *See id.* at 406–07. “Thus, whether section viii is available to a generic manufacturer depends on how the brand describes its patent.” *Id.* at 407.

The use code Corcept submitted for the ’214 patent is “Treating Cushing’s Syndrome.” That use code is, of course, far broader than the method claimed in the ’214 patent. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

But Corcept instead submitted an overbroad and improper use code so it could list the patent in the Orange Book and delay generic competition. *Cf. Caraco*, 566 U.S. at 419 (“An overbroad use code therefore

throws a wrench into the FDA's ability to approve generic drugs as the statute contemplates.”).⁵

Corcept should not be permitted to delay generic competition any longer. Teva's label plainly does not encourage the co-administration of mifepristone and strong CYP3A inhibitors. At most, it provides physicians instructions regarding what to do *if* they decide, in the exercise of their own medical judgment, that co-administration is necessary. Federal Circuit precedent could not be clearer: an instruction in the form “if you do X, then do Y” is *not* an instruction to do X, and it does not actively induce the performance of X. Teva is entitled to summary judgment of non-infringement of the '214 patent.

CONCLUSION

Teva respectfully submits that the Court should deny Corcept's motion for summary judgment of infringement; grant Teva's cross-motion for summary judgment of non-infringement; and dismiss the '214 patent from this lawsuit.

⁵ Even if Corcept had not submitted an improperly broad use code, it is far from clear that [REDACTED]

Dated: May 26, 2021

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